

# **TSCA Risk Management for Existing Chemicals**

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# Overview

- Assessment of Existing Chemicals
  - Risk Evaluations
  - PBTs
  - Pre-Lautenberg Risk Assessments
- Potential Risk Management Options
- Timelines
- Considerations for EPA and Stakeholders



## Risk Evaluations

- TSCA§6(b)(4)(A): EPA shall conduct risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment
  - Without consideration of costs or other nonrisk factors
  - Including an unreasonable risk to a potentially exposed or susceptible subpopulation
  - Under the conditions of use



# Risk Evaluations

- The “First Ten”:
  - Asbestos
  - 1-Bromopropane
  - Carbon Tetrachloride
  - 1, 4 Dioxane
  - Cyclic Aliphatic Bromide Cluster (HBCD)
  - Methylene Chloride
  - N-Methylpyrrolidone
  - Perchloroethylene
  - Pigment Violet 29
  - Trichloroethylene





## Risk Management Deadlines

- TSCA§6(c)(1): If EPA determines that a chemical substance presents an unreasonable risk of injury to health or the environment in accordance with subsection (b)(4)(A), EPA:
  - (A) Shall propose a rule under subsection (a) for the chemical substance not later than 1 year after the date on which the final risk evaluation is published;
  - (B) Shall publish a final rule not later than 2 years after the date on which the final risk evaluation is published.
  - (C) Two-year extension, with limitations, permitted.



## Persistent, Bioaccumulative, and Toxic Chemicals (PBTs)

- TSCA§6(h)(1): EPA shall propose rules under TSCA§6(a) by June 22, 2019, for certain chemical substances identified in the 2014 TSCA Work Plan for Chemical Assessments
  - That are toxic, persistent, and bioaccumulative; and
  - Exposure to which under the conditions of use is likely to the general population, a potentially exposed or susceptible subpopulation, or the environment.
  - PBTs: DecaBDE; HCBd; PCTP; PIP (3:1); 2,4,6-TTBP



## Persistent, Bioaccumulative, and Toxic Chemicals (PBTs)

- TSCA§6(h)(2): EPA shall not be required to conduct risk evaluations on chemical substances that are subject to§6(h)(1).
- TSCA§6(h)(3): EPA shall issue a final rule under §6(a) no later than 18 months after proposing a rule pursuant to§6(h)(1).



## Persistent, Bioaccumulative, and Toxic Chemicals (PBTs)

- TSCA§6(h)(4): In selecting among prohibitions and other restrictions promulgated in a rule under subsection (a) pursuant to paragraph (1), EPA shall:
  - Address the risks of injury to health or the environment that the Administrator determines are presented by the chemical substance; and
  - Reduce exposure to the chemical substance to the extent practicable.





## Chemical Substances With Completed Pre-Lautenberg Risk Assessments

- TSCA§26(l)(4): For a chemical substance on the 2014 Work Plan that had a completed risk assessment published prior to June 22, 2016, EPA may publish proposed and final rules under§6(a) that are consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of§6.



# Risk Management of Existing Chemicals

- TSCA§6(a): Scope of Regulation
  - “If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule and subject to section 18, and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk.”
- TSCA provides authority to regulate:
  - Manufacturers and processors (e.g., formulators)
  - Distributors
  - Commercial users
  - Entities disposing of chemicals for commercial purposes
  - Cannot regulate consumer users; can advise or recommend



## Risk Management of Existing Chemicals

- TSCA §6(a) options:
  - TSCA§6(a)(1): prohibit, limit, or otherwise restrict manufacture, processing, or distribution in commerce.
  - TSCA§6(a)(2): prohibit, limit, or otherwise restrict for particular use or above a set concentration.
  - TSCA§6(a)(3): require clear and adequate minimum warnings and instructions.
  - TSCA§6(a)(4): require recordkeeping, monitoring, or testing.



# Risk Management of Existing Chemicals

- TSCA §6(a) options (cont.):
  - TSCA§6(a)(5): prohibit or regulate manner or method of commercial use.
  - TSCA§6(a)(6): prohibit or regulate manner or method of disposal.
  - TSCA§6(a)(7): direct manufacturers/processors (1) to give notice of the unreasonable risk determination to (A) distributors and other persons in possession of such substance or mixture or exposed to such substance or mixture, (B) to give public notice of the determination, and (C) to replace or repurchase such substance or mixture.





## Risk Management of Existing Chemicals

- TSCA§6(c)(2)(A), (B): In selecting among prohibitions and restrictions, to the extent practicable, the Administrator shall factor in the following considerations:
  - The effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture;
  - the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture;
  - the benefits of the chemical substance or mixture for various uses;
  - the reasonably ascertainable economic consequences of the rule, including consideration of:
    - The likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health;
    - The costs and benefits of the proposed regulatory action; and
    - The cost effectiveness of the proposed regulatory action.



# Risk Management of Existing Chemicals

- TSCA§6(c)(2)(C): Alternatives
  - The Administrator shall consider whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.



## Exemptions

- TSCA§6(g)(1): The Administrator may grant an exemption from a§6(a) requirement if he/she finds that:
  - (A) the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure;
  - (B) compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or
  - (C) the specific condition of use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.



# Final Agency Actions

- TSCA§6(i): Final Agency Actions
  - (1) A determination by the Administrator under subsection (b)(4)(A) that a chemical substance does not present an unreasonable risk of injury to health or the environment shall be issued by order and considered to be a final agency action, effective beginning on the date of issuance of the order; and
  - (2) A final rule issued under subsection (a), including the associated determination by the Administrator under subsection (b)(4)(A) that a chemical substance presents an unreasonable risk of injury to health or the environment, shall be considered to be a final agency action, effective beginning on the date of promulgation of the final rule.





## Relationship to Other Federal Laws

- TSCA§9(a): Laws Not Administered by the Administrator
  - If a chemical substance is found to present an unreasonable risk of injury to health or the environment; AND
  - The Administrator, in his/her discretion, determines that such risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by EPA,
    - The Administrator shall submit to the agency which administers such law a report which describes such risk and specifies the activity which EPA has reason to believe so presents such risk.



## Relationship to Other Federal Laws

- TSCA§9(a) (cont.)
  - If the agency (A) issues an order declaring that the activity does not present the risk described in the report or (B) initiates action under the law(s) administered by such agency to protect against such risk, EPA may not take any action under§6(a) or 7 with respect to such risk.
  - If the agency does not take the actions above, EPA shall (A) initiate or complete appropriate action under§6; or (B) take any action authorized or required under§7, as applicable.



## Relationship to Other Federal Laws

- TSCA§9(b): Laws Administered by EPA
  - The Administrator shall coordinate actions taken under TSCA with actions taken under other Federal laws administered in whole or in part by EPA.
  - If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in his/her discretion, that is in the public interest to protect against such risk by actions taken under TSCA.



# Timelines

- 2019
  - Final rule on methylene chloride
  - Proposed rule to address certain PBT chemicals
  - Final first 10 risk evaluations; initiate risk management if warranted
  - Designate 20 High-Priority and 20 Low-Priority chemicals (December 2019)
- 2020
  - Proposed risk management rules on the first 10 risk evaluations (December 2020)
  - Final PBT rule (December 2020)
- 2021
  - Final risk management rules on the first 10 risk evaluations (December 2021)





# Considerations for EPA and Stakeholders

- Universal considerations:
  - Apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk.
  - What are the costs and benefits of the potential restrictions and prohibitions, including to small business?
  - Will technically and economically feasible alternatives that benefit health or the environment be reasonably available as a substitute?
  - Can an exemption apply, including whether:
    - a critical or essential use for which no technically and economically feasible safer alternative is available; or
    - the requirement would significantly disrupt the national economy, national security, or critical infrastructure?



# Considerations for EPA and Stakeholders

- Pre-Lautenberg Risk Assessments
  - Proposed and final rules need to be consistent with the scope of the completed risk assessment.
  - Apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk.
  - Could other federal laws prevent, eliminate, or reduce unreasonable risk?



# Considerations for EPA and Stakeholders

- PBTs
  - Address the risks of injury to health or the environment; and
  - Reduce exposure to the chemical substance to the extent practicable.



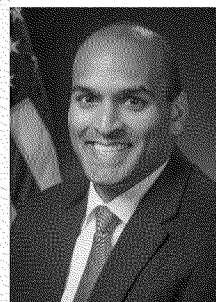
# Considerations for EPA and Stakeholders

- Risk Evaluations
  - Apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk.
  - Identify the particular risk under the condition of use
  - What requirements are necessary:
    - Prohibit, limit, or restrict chemical substance
    - Prohibit, limit, or restrict particular use or concentration of chemical substance
    - Require warnings and/or labels
  - Could other federal laws prevent, eliminate, or reduce unreasonable risk?





# Questions?



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